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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,105	10/09/2001	Jeffrey H. Baxter	6815.US.01	5606
25755	7590	07/25/2006	EXAMINER	
ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES DEPARTMENT 108140-DS/1 625 CLEVELAND AVENUE COLUMBUS, OH 43215-1724			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/973,105

Applicant(s)

BAXTER, JEFFREY H.

Examiner

Isis Ghali

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/12/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/15/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

The receipt is acknowledged of applicant's request for amendment filed 05/12/2006, and IDS filed 05/15/2006.

Claims 2, and 7-43 have been canceled.

Claims 1, 3-6 are pending and included in the prosecution.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 10/266,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the claims of the copending application are directed to method for providing glutamine supplementation to a human comprising oral administration of N-acetyl-L-glutamine. The difference between the present claims and the claims of the copending application is that the present claims are directed to liquid composition and the claims of the copending application are not reciting any specific form of the composition. Therefore, the liquid composition of the present claims anticipates the composition of the claims of the copending application that encompasses liquid as well as any other compositions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Specification***

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Rejections - 35 USC § 102***

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 540 462 ('462).

EP '462 disclosed liquid nutritional formulation comprising N-acetyl-L-glutamine salts (abstract; page 2, lines 42-44, 55-58; page 3, lines 57-58). The amount of glutamine given ranges from 0.1 to 70 g/kg/ day (page 3, lines 9-15), and this amount is calculated to be equal to 0.532 to 37.24 mmol/kg/day, i.e. applicant' claimed amounts fall within the disclosure of the reference. The reference further disclosed that the formulation could contain only L-glutamine as the source of glutamine (page 5, claims 5 and 8). When glutamine added to drink, it does not inhibit gastric emptying to a physiological significant degree, and accordingly secures maximum fluid and nutrient availability (page 2, lines 49-50).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '462 in view of US 3,178,342 ('342).

The teachings of EP '462 are discussed above. However, EP '462 does not teach the specific salts of glutamine as claimed in claim 5.

US '342 teaches dimethyl ethanol amine salt of acetyl glutamine given orally and has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system (col.1, lines 1-18, 46-50; col.2, lines 66-67; 71; col.3, lines 1-4; claims 1-3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition comprising nutrient solution comprising N-acetyl-glutamine salt as disclosed by EP '462, and select the dimethyl ethanol amine salt of acetyl glutamine disclosed by US '342, motivated by the teaching of US '342 that dimethyl ethanol amine salt of acetyl glutamine given has remarkable effect on motor system and psychic development of the human being without affecting the autonomous nervous system, with reasonable expectation of having solution comprising dimethyl ethanol amine salt of acetyl glutamine that while providing nutrients to the human being will simultaneously provide remarkable effect on motor system and psychic development without affecting the autonomous nervous system.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP '462 in view Klimberg et al.

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The teachings of EP '462 are discussed above. However, EP '462 does not teach the conditions that human being could be suffering and therefore given the glutamine containing supplement.

Klimberg teaches that oral glutamine accelerates healing of the small intestine and it is essential dietary component for the gut mucosa (page 1040, left column; page 1042, right column).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition comprising nutrient solution comprising N-acetyl-glutamine salt as disclosed by EP '462, and use the nutrient solution in patient with gut deterioration as disclosed by Klimberg et al., motivated by the teaching of Klimberg et al. that oral glutamine accelerates healing of the small intestine and it is essential dietary component for the gut mucosa, with reasonable expectation of having nutrient solution comprising N-acetyl-glutamine salt used to accelerate healing of compromised small intestine from any disease or particular treatment.

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 1, 3-6 have been considered but are moot in view of the new ground(s) of rejection.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595.

The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

IG

*Isis Ghali*

**ISIS GHALI**  
**PATENT EXAMINER**